

Application No. 08/607,903, filed February 27, 1996, now issued as U.S. Patent No. 5,876,453, which claimed priority of PCT/95/15,576, filed November 30, 1995, and which is a continuation-in-part of U.S. Application No. 08/351,204, filed November 30, 1994, now abandoned."

#### REMARKS

Claims 11-50 remain in the application for further prosecution. The above amendment to the specification is being made to correct the description of the parents of the present application. This description relates to the Examiner's objections to the incorporation of subject matter from application 08/607,903 and to the declaration previously submitted, which is being replaced by a new declaration enclosed herewith. An explanation may be helpful.

The specification was amended previously to add a definition of the term "native oxide layer" as used herein. The definition was transferred from the parent of the present application, which issued as US 5,876,453, and found at column 4, lines 1-30. The Examiner objected to the incorporation of subject matter from 08/607,903, which has a filing date of February 27, 1996 on the grounds that the present application also relies on provisional application 60/009,950, filed January 4, 1996 and therefore was earlier than the '903 application. The present application is a CIP of the '903 application as well as a complete application based on the '950 provisional application. Therefore, it is believed that the Applicants are entitled to incorporate the subject matter from the '903 application. In a preliminary amendment dated March 11, 1999 an extended selection from the '903 application was introduced without objection and the additional material submitted in the previous amendment also appears to be proper. In a review of the chain

of parent applications, it came to our attention that, contrary to the Examiner's earlier objection (see paper 6, 12/17/99) PCT/95/ 15,576 is part of the chain of parent applications. In fact, the text of the PCT application is the same as that of 08/607,903 except for the claims and minor revision of Example 3. The '903 application claimed priority of PCT/95/15,576, filed November 30, 1995, which designated the United States. The Examiner had requested that the PCT application be included in the list of parents of the '903 application, which was done and a revised declaration was submitted. An amended filing receipt was issued showing the PCT application. For an unexplained reason the issued patent, U.S. 5,876,453, did not show a reference to the PCT application on its face. A request for a Certificate of Correction has recently been submitted for U.S. 5,876,453 in order to include reference to the PCT application. Because it appears that the PCT application should be included in the list of parents of the present application, a new declaration has been prepared and it is enclosed herewith. The new declaration includes applications 08/778,503 and 08/351,204 in addition to the provisional application 60/009,952 and PCT/95/15,576. The declaration and the amended specification are now consistent and complete.

The Examiner objected that the declaration did not include an acknowledgement of the Applicant's duty to disclose information known to be material to patentability occurring between the filing date of the prior applications and the filing date of the CIP application. This objection is not understood since the declaration includes such a statement on the first page.

Claims 11-21 and 27-50 were rejected under 35 USC 112, first and second paragraphs, with reference to the use of the term "substantially" in connection with the

removal of native oxide and the forming of a uniform roughness on a surface. With the addition of the information from parent application 08/607,903 the Applicants have provided a basis for defining "native oxide" and how one could determine when it had been removed. In part, a native oxide layer is defined with respect to the results of Auger electron spectroscopy, as illustrated in Fig. 5. Thus, one skilled in the art would be able to determine whether or not the native oxide layer had been removed. In general, the use of the term "substantially" is urged to be as accurate as the subject matter will permit. The use of Auger spectroscopy would enable one skilled in the art to determine from the Applicant's teachings that the metal surface was ready to be given a further treatment to provide the desired uniformly roughened surface. If the native oxide layer is not fully removed the second etching of the surface will not be uniform.

The term "substantially" has also been used with respect to the description of the roughened surface for the same reasons. It should be evident from the photographs of titanium surfaces that the surface cannot be said to be perfectly uniform, since it is produced by the action of acids on the titanium metal and will be affected by several factors. One skilled in the art would understand that removing the native oxide would provide a titanium surface which would be attacked by acids in a more uniform manner. A more accurate description of the nature of the roughened surface does not appear feasible. Consequently, the Examiner is asked to reconsider and withdraw his rejections.

Claims 11-16, 22-25, 27-33 and 35-49 have been rejected under 35 USC 102(b) or 35 USC 103(a) based on the Krueger '434 patent. Reconsideration of this rejection is requested. The teachings of Kruger are vague and the Applicants contend that one skilled in the art could not find even a suggestion of their invention. Consider first the metal

used for the implant. The Applicants were concerned with titanium which has a natural surface oxide coating, referred to in the specification as the "native oxide". In contrast, Kruger says, at column 3, at line 40, "...a unitary member of a biocompatible or reasonably biocompatible material such as titanium or the like...". Even assuming that Kruger's implant was made of titanium, it is not clear that he considered the native oxide, merely referring to 'surface contaminants or impurities on the surface" at column 3, lines 54-55. Then, Kruger failed to provide information on how the etching was to be done. He says at column 3, lines 65 et seq, "The etching techniques which can be used in etching the surface 12 can correspond to those used in etching the electrodes of electrolytic capacitors. For this reason they are not set forth in detail in this specification. Normally, concentrated mineral acids are employed to etch such electrodes."

The Examiner seems to argue that the etched product of Kruger would have its native oxide layer removed and have irregularities of less than 10 microns. The Applicants contend that Kruger is insufficient to make even a *prima facie* case of obviousness and could not be fairly said to anticipate the Applicant's claims. The Applicant's invention is an implant from which native oxide has been substantially removed and thereafter roughened to produce a uniform array of irregularities. Kruger does not even suggest such sequential treatments. Instead he indicates that etching with undefined "mineral acids" would be used. It is clear that Kruger's invention relates to the structure of the implant, not to the etching process. If one skilled in the art were to attempt to follow the teachings of Kruger it is more likely that the Applicant's surface would not result, since that person would have no information on how to proceed. The Examiner has suggested that the Applicants should show that one following the teachings

of Krueger would not produce the same result as is presently claimed. Although providing comparative data would be an appropriate response, the Applicants submit that the Krueger patent provides insufficient information from which they could proceed. Simply put, Krueger's teachings lack the needed details. In his response to the Applicant's arguments, the Examiner has taken the position that any acid treatment such as those suggested by Krueger inherently would remove the native oxide layer. The Applicants have reported in Examples 1 and 2 that treatment with the same acid mixture used to roughen a titanium surface is not sufficient to remove all of the native oxide and that the surface is not uniformly roughened. If the Examiner is correct, it follows that the Applicant's two step process is unnecessary to achieve the desired results. The Examiner is asked to reconsider his comments; he reads too much into the vague disclosure of Krueger.

Claims 26, 34, and 50 have been rejected under 35 USC 103(a) as unpatentable over Krueger in view of Wagner. As the Examiner has admitted, Krueger does not teach the use of both roughened and unroughened portions of an implant. In fact, he suggests that the entire implant should be roughened (see column 3, lines 50-53). Wagner suggests a different approach, that is to use porous material at the base of the implant, with a grit blasted portion above, leaving the top smooth. For most embodiments, Wagner does not use threads, but in Figure 4 an alternative is illustrated which appears to have threads which are not roughened. Thus, combining Wagner with Krueger would not suggest the specific relation between the top and the threaded portions of the Applicant's implant.

In view of the amendments made above and the remarks relative to patentability of the invention over the cited art, the Applicants believe that the claims are in condition for allowance. If the Examiner believes that further amendment is needed, he is invited to contact the Applicants' attorney at the telephone number given below.

Respectfully submitted,

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